

REMARKS

Claims 1-32 are pending in the application. Claims 1-9, 12-26 and 29-32 are rejected. Claims 10, 11, 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No claims are allowed.

Reconsideration of the claim rejections and allowance of all the pending claims in view of the following remarks are respectfully requested.

Claim Rejections – 35 U.S.C. § 103

a. Claims 1-8, 16-21 and 23-26 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pagay et al., US 5,411,488 ("Pagay") in view of Horita et al., US 6,796,216 ("Horita"). Independent claim 1 is directed to a flush syringe assembly comprising, *inter alia*, means for moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to the barrel has stopped. Independent claim 23 is directed to an I.V. flush syringe assembly comprising, *inter alia*, structure for moving additional flush solution distally in the passageway of the barrel after flush solution has been delivered from the chamber and distal motion of the plunger with respect to the barrel has stopped, the structure including the stopper having a distal end including a distal wall and a cavity therein defining an inside surface and a proximal end, the distal wall being flexible enough to collapse at least partially into the cavity under the liquid pressure and to move back toward its original shape at the completion of the flush procedure to force additional flush solution of at least 0.001 ml into the passageway when the syringe is connected to a peripheral catheter.

According to the Examiner, Pagay discloses:

a barrel (20, the barrel) including a cylindrical side wall (21) having an inside surface defining a chamber for retaining fluid, an open proximal end (24, the open end located near the finger grips) and a distal end (22, tapered tip) including a distal wall with a tip extending distally therefrom having a passageway (Fig. 2, the barrel) therethrough in fluid communication with said chamber; a plunger (50, plunger) including an elongate body portion having a proximal end and a distal end, a stopper (30) slidably positioned in fluid-tight engagement with said inside surface of said barrel for driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel.

The Examiner acknowledges that Pagay fails to teach means for moving additional fluid distally, but states:

Ho teaches means for moving (Fig. 5A-D, plunger rod tip) additional fluid distally in said passageway at the completion of the flush procedure after distal motion of said plunger with respect to said barrel has stopped.

The Examiner concludes:

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the design as taught by Ho, since Ho states at column 1, lines 45-64 that such modification would reduce dripping. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in Ho, to improve the device of P for the predictable result of reducing mess formation when using the device.

Applicants respectfully traverse this basis for rejection.

Claim 1 is written in means-plus-language and is directed to a flush syringe assembly comprising, *inter alia*, means for moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to the barrel has stopped. To invalidate a claim reciting a means-plus-function limitation, the reference must disclose the recited function identically. *See Transclean Corp. v. Bridgewood Servs.*, 290 F.3d 1364, 1372 (Fed. Cir.

2002). However, as noted in the MPEP, identity of function is not the only requirement to anticipate or render obvious a means-plus-function claim limitation: one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure. *See In re Donaldson*, 16 F.3d 1189, 1193 (Fed. Cir. 1994). Thus, to determine whether a claim limitation is met, where expressed as a means for performing a stated function, the fact finder must compare the accused structure with the disclosed structure, and must find identical or equivalent structure as well as identity of claimed function for that structure. *See Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987). "[A]bsent structure [in a prior art reference] which is capable of performing the functional limitation of the 'means,' [the prior art reference] does not meet the claim." *In re Mott*, 557 F.2d 266, 269 (CCPA 1977).

Structure provided in the instant specification for moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to the barrel has stopped includes a stopper including a distal end having a distal wall and a cavity therein defining an inside surface and a proximal end, the distal wall being flexible enough to collapse at least partially into the cavity under the liquid pressure of a flush procedure and to move back toward its original shape at the completion of the flush procedure to force additional fluid into the passageway of the barrel. This structure, which is diagrammatically shown in Figures 3-5 (stopper 41, distal wall 62, cavity 59), is the means recited in claim 2 and the structure recited in claim 23. Additional structure which may be provided in addition to the flexible plunger wall to aid in the recited function includes a spring (element 382 in

Figure 12), a projection (element 482 in Figure 15) and a raised rib (element 281 in Figure 11).

According to the Examiner, Horita provides means for moving (Fig. 5A-D, plunger rod tip) additional fluid distally in said passageway at the completion of the flush procedure after distal motion of said plunger with respect to said barrel has stopped. However, this interpretation of Horita is factually incorrect. Horita is directed generally to an injector assembly for use with pasted material in the dentistry field. *See* page 1, paragraphs 0005-0007. The injector assembly comprises a seal member 30 (shown in Figure 4) having a base portion 31 and flange portions 32. *See* page 4, paragraph 0052. As shown in Figures 5A-D of Horita, when seal member 30 is pressed towards the distal end of barrel 10 via plunger 20 so as to discharge the material through the nozzle-like discharge port 11, reaction force from the accommodated liquid affects on the flange portion 32, which is in turn elastically deformed towards the proximal end of the barrel. *See* paragraph 0061. When the discharging operation has been finished by releasing pressing force from plunger 20, flange portion 32 is returned to the initial state by means of self-restoring force of the flange portion 32, and plunger 20 is forced towards the proximal end of barrel 10. *See* paragraph 0062. As a result, according to Horita, "the residual pressure of the liquid caused during the liquid discharging operation is automatically released by means of the restoring action of the flange portion 32, so that leakage (subsequent dropping) of the liquid through the nozzle-like discharge port 11 due to the residual pressure can be effectively prevented." *See* paragraph 0065. Thus, rather than moving additional fluid distally at completion of a flush procedure, seal member 30 in Horita functions in the complete opposite manner, namely drawing fluid proximally after discharge.

Regarding claims 2 and 23, which recite specific structure for performing the recited function, the Examiner states that Pagay discloses said stopper including a distal end having a distal wall (32, convex side) and a cavity (34, interior) therein defining an inside surface and a proximal end, said distal wall being flexible enough to collapse at least partially into said cavity under the liquid pressure of a flush procedure and to move back toward its original shape at the completion of the flush procedure to force additional fluid into said passageway. However, the Examiner has provided no evidence that distal wall 32 is flexible enough to at least partially collapse into cavity 34 under liquid pressure. Indeed, as explained in Applicants' previous submission, a review of Pagay indicates that this is not the case at all.

As shown in Figure 5 of Pagay, plunger tip 64 contacts the inside face 34 of stopper during use. As a result, there is no cavity into which the stopper could partially collapse. Indeed, Figure 5 shows elongation of distal face 32 of the stopper in the distal direction, which aids in movement of the barrel in the distal direction. *See col. 6, line 60 to col. 7, line 2.* Furthermore, similar to Horita, Pagay teaches that upon stoppage of distal motion of the plunger, a vacuum is created in the barrel, which draws fluid into the passageway (see col. 6, lines 56-60). Again, this is the complete opposite of the function recited in claims 1 and 23, namely forcing additional fluid distally at the completion of the flush procedure. As such, Pagay fails to disclose identical or equivalent structure capable of performing the identical recited function.

Since neither Pagay nor Horita disclose structure capable of forcing additional fluid distally at the completion of a flush procedure, Applicants submit the claims 1-4, 16, 17, and 23-25 are not unpatentable over Pagay in view of Horita, and reconsideration of this basis for rejection is respectfully requested.

b. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Pagay and Horita in view of Grimard, US 5,795,337 ("Grimard").¹ The Examiner acknowledges that Pagay and Horita do not explicitly disclose the additional limitations recited in the claims, but states that such limitations are found in Grimard.

Applicants respectfully traverse this basis for rejection.

Claims 9 and 22 each depends from independent claim 1. As discussed above with respect to the rejection of claim 1, Pagay and Horita do not disclose any structure capable of moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to said barrel has stopped. Furthermore, the Examiner has pointed to nothing in Grimard that remedies the deficiencies of Pagay and Horita in this respect. As such, the combination of Grimard with Pagay and Horita cannot render the claimed invention obvious. *See In re Rijckaert*, 9 F.3d 1531, 1533 (Fed Cir. 1993).

Accordingly, Applicants submit the claims 9 and 22 are not unpatentable over Pagay and Horita in view of Grimard, and reconsideration of this basis for rejection is respectfully requested.

c. Claims 12-15 and 29-32 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Pagay and Horita in view of Eykmann et al, US 5,620,423 ("Eykmann").² The Examiner acknowledges that Pagay and Horita do not explicitly disclose the additional limitations recited in the claims, but states that such limitations are found in Eykmann.

¹ Although the Office Action states that the rejection is over only Pagay in view of Grimard, Applicants assume the Examiner also meant to include Horita in the rejection.

² Although the Office Action states that the rejection is over only Pagay in view of Eykmann, Applicants assume the Examiner also meant to include Horita in the rejection.

Applicants respectfully traverse this basis for rejection.

Claims 12-15 each depends from independent claim 1, and claims 29-32 each depends from independent claim 23. As discussed above with respect to the rejections of claims 1 and 23, Pagay and Horita do not disclose any structure capable of moving additional fluid distally in the passageway of the barrel at the completion of the flush procedure after distal motion of the plunger with respect to said barrel has stopped. As explained in Applicants' previous submission, contrary to the Examiner's assertion, nothing in Eykmann remedies the deficiency of Pagay in this respect.

Each of claims 12-15 and 29-32 requires a stopper including a distal end having a distal wall with a proximally directed projection projecting into a cavity defined therein, the projection configured to compress when the stopper is in a collapsed position and to urge the distal wall of the stopper from the collapsed position to its original shape at the completion of the flush procedure, thereby forcing additional fluid into the passageway of the barrel. In contrast, stopper 6 shown in Figure 2 of Eykmann is prestressed in the proximal direction, which is its initial shape after it has been displaced after cartridge 2 has been filled with a viscous material, as shown in the right side of Figure 3. *See col. 5, lines 36-39.* After engagement by rotary piston 4, stopper 6 curves in the opposite direction, i.e., in the distal direction, as shown in the left side of Figure 3. *See col. 5, lines 45-48.* After delivery of the desired quantity of material, rotary piston 4 is turned in the opposite direction, thereby removing pressure from stopper 6, allowing it to return to its original shape. *See col. 5, lines 56-62.* As Eykmann teaches, this generates an underpressure, which pulls the material which is still in discharge opening 23 of discharge nozzle 9 back into cartridge 2, thereby preventing running or dripping of material. *See col. 5, lines 62-67.*

Thus, the original shapes of the stoppers in the instant claims (extended distally) vs. Eykmann (collapsed proximally) result in different functions. That is, rather than forcing additional fluid into the passageway of the barrel after distal motion of the plunger has stopped, as recited in the instant claims, the stopper in Eykmann, similar to the stopper in Horita discussed above, performs the complete opposite function, namely drawing material into the barrel after distal motion of the plunger has stopped. As such, the combination of Eykmann with Pagay and Horita cannot render the claimed invention obvious. *See Rijckaert*, 9 F.3d at 1533.

In addition, contrary to the Examiner's assertion, the missing limitations of claims 12-15 and 29-32 are not found in Eykmann. Claims 12 and 29 each requires that the inside surface of the stopper include a proximally directed projection configured to compress when the stopper is in a collapsed position and to urge the distal wall from the collapsed position toward its original shape. One embodiment is diagrammatically shown in Figure 15 (element 482) of the subject application. The Examiner states that Figure 2 of Eykmann shows a proximally directed projection, but Figure 2 merely shows stopper 6, with no indication of a proximally directed projection attached thereto.

Claims 13 and 30 each requires at least one rib on the inside surface of the stopper at the distal wall configured to deflect when the stopper is in a collapsed position and urge the distal wall from the collapsed position toward its original shape. One embodiment is diagrammatically shown in Figures 10 and 11 (element 281) of the subject application. The Examiner states that element 15 in Figure 2 is the claimed rib, but element 15 is not on the inside surface of the stopper, as required by the claims, but rather on the outside surface.

Claims 14, 15, 31 and 32 each requires that the distal wall have an area of reduced thickness to lower the pressure required for the distal wall to collapse. One embodiment is diagrammatically shown in Figures 8 and 9 (elements 168 and 169) of the subject application. The Examiner states that element 13 in Figure 2 is the area of reduced thickness, but Eykmann teaches that the original position of stopper 6 is collapsed (*see* col. 4, line 67 to col. 5, line 2), meaning element 13 does not function to lower the pressure required for the distal wall to collapse during distal movement of the plunger.

Accordingly, Applicants submit the claims 12-15 and 29-32 are not unpatentable over Pagay and Horita in view of Eykmann, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 1-32 are now in condition for allowance, early notice of which would be appreciated. The Examiner is authorized to charge any additional fees or credit any overcharges to Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

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Respectfully submitted,

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